a lavender colored powder that changes to burgundy-red in gastric juice at pH 1.5-2.5. This causes the shell or wall of the protective gel-structures to turn burgundy-red (indicating acid pH) while the inner contents stay lavender or becomes blue-purple (indicating alkaline pH). This feature allows practitioners and sales professionals to visually demonstrate the formulation's characteristics and effectiveness.

REMARKS

Regarding the Section 102(e) rejection over McGrath et al., the Examiner stated that:

> The formulation of MGrath et al. is the same as the claimed composition. Since the claims are drawn to a formulation, *characteristics* such as "upon exposure to an acidic environment, an alginic acid gel is formed which shields the probiotic bacteria from the antibiotic effects of the acidic environment," the ratio of sodium alginate, drying the formulation are viewed *as process limitations*. [emphasis added]

Applicant is entitled to be his own lexicographer, and to claim an invention as he/she sees fit. There is no basis in law or rule to disregard "process limitations" in a claim in determining patentability. Moreover, as the Examiner states in the above-quoted section, the fact that alginic acid gel forms is a *characteristic* of the claimed formulation – and Applicant agrees. A "process" is generally related to 'making' of the invention. The Examiner has not contended that one cannot rely on a *characteristic* or a property to distinguish claimed subject matter. Patentability is established, of course, where the properties of the claimed composition are different than those in the prior art. *See, for example*, MPEP 2144.09 (under a related heading): "The presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds."

However, irrespective of how one chooses to characterize the term in question, it is proper to include it in a claim and rely on it. For example, even where an intended use is set forth in the preamble of a claim, it may distinguish the subject matter for purposes of patentability. *See* MPEP 2111.01 (last paragraph):

> During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim.

Moreover, courts have held that "process limitations" are entirely appropriate for describing claimed subject matter. *See* MPEP 2113:

> The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

Process limitations, for example in a product-by-process claim, have been used in United States patent practice since time immemorial. There is no basis to disregard a "process limitation" in assessing patentability.

Applicants have included a declaration by the Applicant to establish that the formulation in McGrath et al. does *not* form "upon exposure to an acidic environment, an alginic acid gel ... which shields the probiotic bacteria from the antibiotic effects of the acidic environment." Accordingly, there is a clear difference between the claimed composition and that of the prior art, and the anticipation rejection of claims 1-6 and 8-13 should be withdrawn. Moreover, it is clear that claim 2, reciting that the formulation: "does not include alginate salts of divalent metals, in quantities such that the shielding alginic acid gel does not form," is allowable, even if the objection to "process limitations" is maintained. There is no question but that the exclusion of alginate salts of divalent metals is a characteristic of the formulation itself, and is not a "process."

Applicants have also amended claims 8 and 9 to delete reference to a "derivative of cellulose," and inserted "Vcaps™" instead in claim 8, which is used e.g., on page 14,

line 13 of the specification. Vcaps are made of Hydroxypropyl Methylcellulose (see the Capsugel website) which is a "derivative of cellulose." Accordingly, the rejections under Section 112 paras. 1 and 2 should be withdrawn.

Applicants have also corrected the word "shin" in the specification. The Examiner is thanked for noting this error and bringing it to our attention.

In conclusion, all claims are now allowable, and such action is sought.

Respectfully submitted,

Dated: 8/16/05

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Applicant hereby petitions for any petition required to make this submission timely and in compliance with applicable rules. The Commissioner is hereby authorized to charge any fees due in connection with this submission and not otherwise covered by payment included herewith, or to credit any overpayment, to Deposit Account No. 502088.